hybridoma selected from the group consisting of FERM BP-5383, FERM P-14879 and FERM P-14880, and said monoclonal antibody is an IgM isotype.

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the foregoing amendment, claim 13 has been canceled without prejudice or disclaimer to the subject matter recited therein. Claim 10 has been amended to further clarify Applicants' invention. Support for the amendment can be found in canceled claim 13. Accordingly, no new matter has been added.

I. Rejections Under 35 U.S.C. 102(b)

Claims 10 and 11 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Stein et al. (*Hybridoma*, 7:555-67, 1988). Applicants respectfully traverse this rejection.

It is well settled law that to anticipate a claim, a single reference must teach each and every element of the claim, and the single reference must be enabling. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984).

The Examiner has stated that Stein et al. discloses an antigen from the Calu3 human lung andenocarcinoma cell line with a molecular weight of greater than 300kDa. The Examiner has further stated that the specification discloses that antibodies which bind the claimed antigen were obtained by using the culture broth of the Calu3 cell line, hence the antigen disclosed by Stein et al. may be the identical antigen of the instant invention, having the same inherent properties such as the binding of particular lectins and monoclonal antibodies.

In order to expedite prosecution in the subject application and not acquiesce to the Examiner's rejection, Applicants have amended claim 10 to recite that the monoclonal antibody is an IgM isotype. Stein et al. does not teach or disclose this feature. In fact, the monoclonal antibody of Stein et al. is an IgG_1 isotype. See the Abstract and page 560 of Stein et al.

Therefore, because Stein et al. does not teach, either explicitly or inherently, each and every element of the claimed invention, Applicants respectfully request withdrawal of the rejection of claims 10 and 11 under 35 U.S.C. § 102(b).

Claim 10 has also been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gorbachev et al. (*Biokhimiya*, 59:1401-5, 1994) as evidenced by De Robertis and De Robertis (Cell and Molecular Biology, 7th Ed., pp. 235-7, 1975). Applicants respectfully traverse this rejection.

The Examiner has stated that Gorbachev et al. discloses a glycoprotein antigen associated with human lung adenocarcinoma cells having a molecular weight of 400 kD and that the claimed antigen appears to be the same as the prior art antigen.

As stated above, in order for a reference to anticipated a claimed invention, the reference must teach each and every element of the claim, and the single reference must be enabling.

Applicants submit that Gorbachev et al. does not teach, either explicitly or inherently, each and every element of the claimed invention, and the reference is not enabling. Specifically, Gorbachev et al. fails to teach a 200 kDa secreted protein that binds to a monoclonal antibody produced by a hybridoma selected from the group consisting of FERM BP-5383, FERM P-14879 and FERM P-14880 and that the monoclonal antibody is an IgG isotype.

The Examiner asserts that De Robertis teaches that the fate of all glycoproteins is exocytosis at the plasma membrane and therefore, all glycoproteins can be considered as secreted from the cell. Applicants respectfully disagree.

Figure 11-7 of De Robertis depicts secretory and plasma membrane glycoproteins being exocytosed from the cell. However, only the secretory glycoproteins are secreted. The plasma membrane glycoproteins are not secreted, but instead are incorporated into the plasma membrane. In fact, De Robertis states that "[i]n addition to the glycoproteins that are secreted and those that are incorporated into the plasm membrane are others that become incorporated into lysosomes." See page 236, column 1, fourth full paragraph, of De

Robertis et al. Thus, according to the teachings of De Robertis, there are potentially three types of glycoproteins, those that are secreted, those that are incorporated into the plasma membrane and those that are incorporated into lysosomes.

Applicants further submit that the use of De Robertis is improper. The law permits the use of extrinsic evidence to interpret or explain the disclosure of the prior art reference. *See Scripps Clinic*, 927 F.2d 1576, 18 U.S.P.Q.2d at 1010 (Fed. Cir. 1991); *see also In re Graves*, 69 F.3d 1147, 1152, 36 U.S.P.Q.2d 1697, 1701 (Fed. Cir. 1995). Such evidence, however, cannot be used to expand or fill in gaps in the teachings of the references. Here, the Examiner is relying on De Robertis to establish that the antigen of Gorbachev et al. is secreted, an element of the claimed invention which Gorbachev et al. fails to teach. This element cannot be "filled in" by De Robertis.

As stated above, Gorbachev et al. fails to teach each and every element of the claimed invention. Gorbachev et al. does not teach a 200 kDa secreted protein that binds to a monoclonal antibody produced by a hybridoma selected from the group consisting of FERM BP-5383, FERM P-14879 and FERM P-14880 and that the monoclonal antibody is an IgG isotype. Even if one considers the teachings of De Robertis in combination with Gorbachev et al., the skilled artisan does not know whether the antigen of Gorbachev et al. is secreted, incorporated into the plasma membrane or incorporated into lysosomes. Further, these references are not enabling.

Therefore, because neither reference teaches, either explicitly or inherently, each and every element of the claimed invention, Applicants respectfully request withdrawal of the rejection of claim 10 under 35 U.S.C. § 102(b).

Applicants acknowledge the Examiner's statement that claims 12, 13, and 15 are allowed. In light of the above, claims 10 and 11 are also believed to be allowable. Accordingly, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Susan M. Dadio
Registration No. 40,373

P.O. Box 1404
Alexandria, VA 22313-1404
(703) 836-6620

Date: October 23, 2001

Attachment to Amendment and Reply dated October 23, 2001
Marked-up claim 10

10. (Twice Amended) A glycoprotein antigen having a molecular weight of 200 kD or more as determined by SDS-PAGE under reducing conditions, which is expressed by cells of human lung adenocarcinoma, and is secreted by said lung adenocarcinoma, wherein said glycoprotein antigen specifically binds to a monoclonal antibody produced by a hybridoma selected from the group consisting of FERM BP-5383, FERM P-14879 and FERM P-14880, and said monoclonal antibody is an IgM isotype.